

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dallas L. Cloutre
Title: (-)-HYDROXYCITRIC ACID FOR
CONTROLLING INFLAMMATION
Appl. No.: 10/612,648
Filing Date: 7/2/2003
Examiner: Zohreh A. Fay
Art Unit: 1612
Confirmation Number: 3676

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the **Pre-Appeal Brief Conference Pilot Program**, announced July 11, 2005, this Pre-Appeal Brief Request is being filed together with a Notice of Appeal and the required Notice of Appeal fee. This communication is responsive to the Final Office Action dated May 17, 2010, concerning the above-referenced patent application. With the accompanying petition for a one-month extension of time, this response is timely filed.

Claim Rejections Under 35 U.S.C. §§ 102(b) and 102(e)

In the Final Office Action, claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Hastings *et al.* (U.S. 5,626,849). Claims 4-6 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Cloutre *et al.* (U.S. 6,447,807). Applicants

respectfully traverse the rejections. As discussed in more detail below, the §102 rejections are based on the Examiner's position that the cited references inherently anticipate the claimed invention. However, the requirements for inherent anticipation have not been met.

To anticipate under the doctrine of inherency, the missing descriptive matter must be *necessarily present* in the thing described in the reference. *See, e.g., Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1369 (Fed. Cir. 2003); *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999); *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Anticipation by inherency cannot be based on probabilities or possibilities that something “may” happen. *See, e.g., Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002); *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999). The fact that a certain thing “may” result (but not “necessarily”) is not sufficient to establish inherency. *See, e.g., In re Cruciferous Sprout Litig.*, 301 F.3d at 1349 (quoting *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999)); *In re Robertson*, 169 F.3d at 745. *See also* MPEP § 2112.

First, it is clear that none of the cited references *expressly* disclose a method of treating or ameliorating chronic inflammation by orally administering a therapeutically effective amount of (-)-hydroxycitric acid, as recited in independent claim 1. *Hastings et al.* teach the use of (-)-hydroxycitric acid for the purpose of weight loss. Likewise, *Clouatre et al.* is cited for teaching the use of potassium and sodium salts of (-)-hydroxycitric acid in a sustained release formulation for weight loss.

Second, the cited references also do not *inherently* teach the claimed methods. The Examiner contends that the use of (-)-hydroxycitric acid for weight loss would inherently treat and ameliorate any inflammation in the body because there “has to be some type of inflammation in the body at any given moment.” Non-Final Office Action, dated August 13, 2009. In support of this position, the Examiner cites an article by Marcelle Pick, “Causes of inflammation,” <http://www.womentowomen.com/inflammation/causes.aspx>, herein “Pick”. Referring to this article, the Examiner states that “inflammatory process in the body can be caused with any types

of imbalance, even such imbalance caused by the intake of certain food products. Therefore, the human boy [*sic*] is always dealing with certain type of inflammation which can be silent and not obvious to the eye.” Office Action, dated January 7, 2009, p. 2.

Applicants respectfully submit that the teachings of Pick have been misapprehended. Nowhere does Pick teach or suggest that inflammation is always present in the body. Rather, Pick asserts that certain foods, allergens, hormonal changes, stress, and environmental factors can contribute to inflammation. A careful reading of Pick shows that while there may be many causes of inflammation, it is possible to control inflammation through appropriate lifestyle changes. According to Pick:

While the incidence of inflammation and inflammatory disease is rising in all developed countries, it's important to remember that each of us has an individual response to the stressors in our life. Some of that unique response is determined by genetics. But much of it is within our control—if we understand how our choices affect our health.

You can see that controlling chronic inflammation takes a combination approach because it arises from a combination of causes. The good news is that so much of it is in your control.

Pick, p. 5, ¶¶ 2-3. The above passage makes clear that inflammation in each individual depends on a variety of factors, including genetics. It is not a certainty that all human subjects will suffer from inflammation all of the time. In other words, the reference does not support the Examiner's position that “there has to be some type of inflammation in the body at any given moment.”

Because Pick does not show that the patients treated for weight loss in Hastings *et al.* or Clouatre *et al.* were necessarily suffering from chronic inflammation, the Examiner has provided no convincing evidence that the use of (-)-hydroxycitric acid for weight loss would inherently treat and ameliorate any chronic inflammation. In order to meet his or her burden under a theory of inherent anticipation, “The examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent

characteristic of the prior art” before the burden is shifted to Applicants to disprove the inherency. *Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986). In the instant application, the Examiner has not yet provided sufficient evidence that the treatment of chronic inflammation with (-)-hydroxycitric acid is an inherent characteristic of the prior art.

Perricone v. Medicis Pharm. Corp., 432 F.3d 1368 (Fed. Cir. 2005) emphasizes this point by illustrating the difference between claims that recite a new use of an old composition and claims that recite a newly recognized benefit of an old method. *Perricone* involved two sets of claims, one directed to preventing sunburn damage and the other to treatment of skin sunburn. In each case, the claims required topical application of a fatty acid ester of ascorbic acid. The prior art described topical application of the same compound (among thirteen others) to skin, in an amount that encompassed the claimed effective amount. The *Perricone* court found that the claims directed to preventing sunburn damage to exposed skin surfaces were anticipated by the prior art, even though the prior art “[did] not disclose any benefit directed to skin sunburn, or any of the other specific skin disorders, as claimed.” *Id.* at 1376. On the other hand, the court found that the claims directed to treating skin sunburn were directed to a new use of the prior art compounds, and therefore not anticipated, because the prior art “[did] not disclose topical application to skin sunburn.” *Id.* at 1379. That is, the prior art did not disclose applying the compound to the same population (people with sunburn) as required by the claims. As the court explained, “[t]he issue is not . . . whether [the prior art] lotion *if applied* to skin sunburn would inherently treat that damage, but whether [the prior art] discloses the application of its composition to skin sunburn.” *Id.* at 1378.

In the present case, the prior art did not disclose applying (-)-hydroxycitric acid to the same population (people with chronic inflammation) as required by the claims. Administering (-)-hydroxycitric acid to a patient suffering from chronic inflammation is not inherent to administering the compound to a subject in need of weight loss. As noted above, the Examiner has not provided any evidence that the subjects described in *Hastings et al.* or *Clouatre et al.* were suffering from chronic inflammation. The Pick reference cited by the Examiner does not

support the contention that the human body is *necessarily* suffering from inflammation at all times. The Examiner's burden under the theory of inherent anticipation has not been met. For at least this reason, Applicants request withdrawal of these rejections.

Applicants also note that although claims 4-6 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Clouatre *et al.* (U.S. 6,447,807), these claims depend from claim 1. However, claim 1 is not rejected based on this reference. It is axiomatic that a dependent claim is directed to a combination including everything recited in the base claim and what is recited in the dependent claim. It is this combination that must be compared with the prior art, exactly as if it were presented as one independent claim. Applicants submit that claims 4-6 cannot be anticipated by Clouatre if claim 1 is not also anticipated. Applicants respectfully request withdrawal of this rejection.

Favorable reconsideration of the application is respectfully requested.

Respectfully submitted,

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